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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/591,164

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Naoki Nagahara

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12/09/2009

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EXAMINER

DICKINSON, PAUL W

ART UNIT

PAPER NUMBER

1618

MAIL DATE

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PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/591,164	<b>Applicant(s)</b> NAGAHARA ET AL.	
	<b>Examiner</b> PAUL DICKINSON	<b>Art Unit</b> 1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 08 September 2009.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-24 is/are pending in the application.
- 4a) Of the above claim(s) 3, 6 and 13 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1, 2, 4, 5, 7-12 and 14-24 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                                | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948)                        | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

**DETAILED ACTION**

***Election/Restrictions***

Applicant's election without traverse of pullulan as the capsule shell main component in the reply filed on 9/8/2009 is acknowledged.

Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objects are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

***New Grounds of Rejection***

***Claim Rejections - 35 USC § 112, Second Paragraph***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-2, 4-5, 7-12, and 14-24 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Regarding claim 1, the term "derivative" renders the claim indefinite because it is unclear how far removed the "derivative" can be from the parent compound without being a different compound entirely.

Regarding claims 15, 16 and 24, a broad range or limitation together with a narrow range or limitation that falls within the broad range or limitation (in the same claim) is considered indefinite, since the resulting claim does not clearly set forth the metes and bounds of the patent protection desired. See MPEP § 2173.05(c). Note the

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explanation given by the Board of Patent Appeals and Interferences in *Ex parte Wu*, 10 USPQ2d 2031, 2033 (Bd. Pat. App. & Inter. 1989), as to where broad language is followed by "such as" and then narrow language. The Board stated that this can render a claim indefinite by raising a question or doubt as to whether the feature introduced by such language is (a) merely exemplary of the remainder of the claim, and therefore not required, or (b) a required feature of the claims. Note also, for example, the decisions of *Ex parte Steigewald*, 131 USPQ 74 (Bd. App. 1961); *Ex parte Hall*, 83 USPQ 38 (Bd. App. 1948); and *Ex parte Hasche*, 86 USPQ 481 (Bd. App. 1949). In the present instance, claims 15, 16 and 24 recite the broad recitation "granules", and the claims also recite "fine granules" which is the narrower statement of the range/limitation.

Regarding claim 21, it is unclear how a coating layer can be a "coating layer within a range of pH 6.0 to pH 7.5". Does this mean that the pH of the coating layer is between 6.0 to 7.5? As written, the claim equates the coating layer with a pH. A coating layer can have a pH, but cannot be a pH. The Examiner recommends deleting "wherein the controlled-release coating layer is a coating layer within a range of pH 6.0 to pH 7.5" and instead reciting "wherein the controlled-release coating has a pH within a range of pH 6.0 to pH 7.5". Such language is definite.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-2, 4-5, 7-12, and 14-24 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 20050181052 ('052) in view of US 6887307 ('307). '052 discloses a pharmaceutical composition comprising microtablets, wherein said microtablets comprise lansoprazole (a medicine unstable to moisture) enclosed inside a capsule shell (see ¶ 1, 13, 61-63, Examples 1-2).

Instant claim 12 is directed to a capsule preparation wherein the PPI is an optically active isomer (R-isomer) of lansoprazole. The capsules disclosed by '052 are a racemic mixture comprising both the R- and S- isomers of lansoprazole (see ¶ 12).

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Instant claim 12 uses open terminology, and does not exclude the presence of more than one optically active isomer (or other components). The racemic mixture disclosed by '052 therefore anticipates the instant claim.

Instant claim 15 is directed to a capsule preparation wherein the content in the capsule is fine granules optionally coated, granules optionally coated and/or tablets optionally coated. The capsules disclosed by '052 contain granules coated with an enteric coating (see ¶ 61; Examples 1-2).

Instant claim 16 is directed to a capsule preparation which contains at least two solid preparations selected from fine granules, granules and tablets in combination. Instant claim 17 is directed to a capsule preparation wherein the combined solid preparations have different medicine release properties. Instant claim 18 is directed to a capsule preparation wherein the solid preparations have a coating layer. '052 discloses two different microtablet formulations, one dried and one undried, both having a coating (see Examples 1-2; Table 1). '052 further discloses that both of these microtablet formulations release lansoprazole, but at different rates (different medicine release properties). Both formulations have the same function (release lansoprazole) and one of ordinary skill in the art would be motivated to use both in combination with each other, affording the instant invention. "It is prima facie obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition to be used for the very same purpose.... [T]he idea of combining them flows logically from their having been individually taught in the prior

art.” In re Kerkhoven, 626 F.2d 846, 850, 205 USPQ 1069, 1072 (CCPA 1980). See MPEP 2144.06, I.

Instant claims 19-24 are directed to limitations of the coating layer in instant claim 18. Instant claim 19 is directed to an enteric coating layer. The capsule preparation disclosed by '052 have an enteric coating layer (see ¶ 61-63; Examples 1-2). Instant claims 20 and 24 are directed to a controlled-release coating layer. The coating layer taught by '052 is a controlled-release coating. Instant claim 21 is directed to a coating layer that is a pH-dependent soluble controlled-release coating film containing a polymer soluble within a range of pH 6.0 to pH 7.5. '052 discloses specific polymers to be incorporated into the enteric coating, including preferred polymers that are water soluble at a pH of 6.5, such as polyvinyl pyrrolidone (see '052, ¶ 19; US 7288174, col 7, ln 4-15). Furthermore, the coating layer taught by '052 is a controlled-release coating layer that is a diffusion-control type controlled-release film (instant claim 22) and a time release type controlled-release coating film (instant claim 23) (see '052, Examples 1-2). These attributes are supported by the release profile disclosed for the capsule preparation (see Table 1).

Although gelatin capsules are disclosed by '052, the reference fails to disclose a capsule shell wherein the main component is pullulan (the elected embodiment).

'307 discloses pullulan film compositions (see abstract). The pullulan capsules of the invention have advantages over traditional gelatin capsules, the advantages including lower oxygen permeability, lower water content, and higher shelf-life stability (see col 3, line 66 to col 4, line 10). Other advantages include higher product quality

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consistency, higher homogeneity, (see *ibid*) and ease of manufacture and capsule filling (see col 6, lines 50-52).

Owing to the susceptibility of lansoprazole to degradation (see '052: ¶ 2), it would have been obvious to search the art to look for capsules that have superior stability over the gelatin capsules of '052. It would have been obvious to use the pullulan capsules of '307 as the capsule shell of '052 as these capsules exhibit low oxygen permeability, lower water content, and high stability. The capsules thus made would read on the capsule preparation of instant claim 1. Such a capsule would be a capsule preparation which comprises a capsule shell (made of pullulan) and contained inside the capsule shell lansoprazole (a medicine unstable to moisture). The capsule preparation thus made has all the structural requirements of instant claim1, and because a composition cannot be separated from its properties, it must inherently be stable in a low moisture state and have pH-independent disintegration properties. “[T]he discovery of a previously unappreciated property of a prior art composition, or of a scientific explanation for the prior art’s functioning, does not render the old composition patentably new to the discoverer.’ *Atlas Powder Co. v. Ireco Inc.*, 190 F.3d 1342, 1347, 51 USPQ2d 1943, 1947 (Fed. Cir. 1999). Thus the claiming of a new use, new function or unknown property which is inherently present in the prior art does not necessarily make the claim patentable. *In re Best*, 562 F.2d 1252, 1254, 195 USPQ 430, 433 (CCPA 1977).” MPEP § 2112, I.



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***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to PAUL DICKINSON whose telephone number is (571)270-3499. The examiner can normally be reached on Mon-Thurs 9:00am-6:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Hartley can be reached on 571-272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Eric E Silverman/  
Primary Examiner, Art Unit 1618

Paul Dickinson  
Examiner  
AU 1618

December 4, 2009